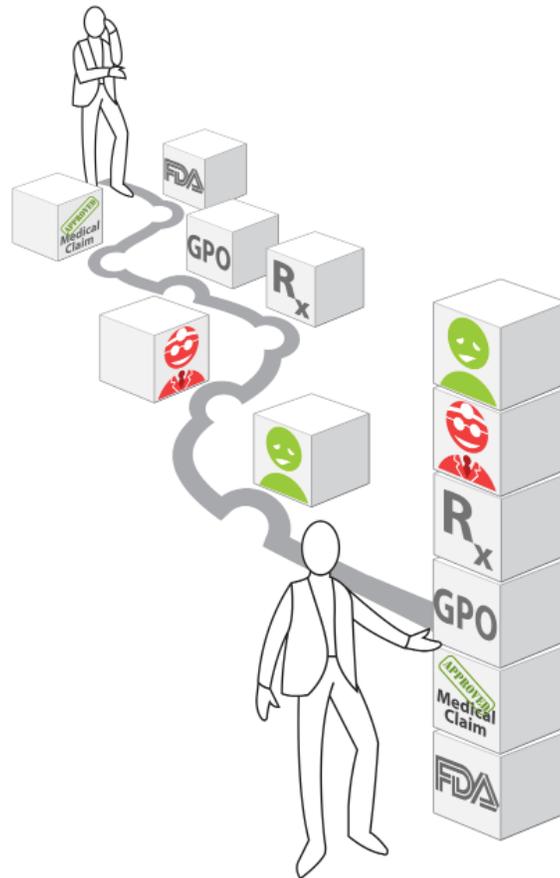


How to Spend Your First \$100,000 of Funding...



...and How NOT to.

**MPR Product Development
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*MPR Product Development
Outsourced Innovation, Design, Engineering & Vision*

It is critical to spend that first \$100K in the right way: demonstrating the feasibility of your device idea

Imagine you are an early stage entrepreneur with a breakthrough technology, some promising intellectual property, and \$100K is on the way from a new investor. What do you need to do to maximize your chances of success? One investor posed it this way, 'This entrepreneur is an unknown quantity, with an interesting breakthrough technology. At this early stage no one is likely to give them the three million they're asking for. However, I might be willing to invest some to move the project ahead...What can be done for \$100K?' Early stage device startups are more likely to gain access to seed capital rather than a large investment, but they often have a problem figuring out how to spend the money in a way that will lead to more funding.

From the investor's viewpoint, breakthrough ideas and unproven management increase risk. New ideas often are too early for "professional money" and new ventures typically do not make it. Based on data, between 2001 and 2010, 30-40% of venture funded high-tech companies went belly-up. The pathway to success for early stage devices is straightforward, but there is little room for error, and there are many ways to get it wrong.

One big reason early stage devices fail is that too much resource is spent on things that aren't directed toward reducing risk. Early stage entrepreneurs often miss the point that their objective is to get the asset ready for the next round of investment. We have met scores of entrepreneurs who had a demonstration prototype, and thought the most important next thing was to refine it in ways that did nothing toward answering the key questions that investors will ask. Early stage device ideas need to demonstrate feasibility in order to become investible. The challenge is reducing risk with very little cash.

Another big mistake is incorporating and hiring staff too early. Generally this is a waste of precious time and money. The organization has gotten ahead of the development maturity of the device. Sales staff are in place, but basic technology and market risks have not been addressed.

The Solution Is...

The solution for how to spend the \$100K is to demonstrate the feasibility of the device. The Market Engagement Model on the next page offers a roadmap for figuring out the critical few things that need to be accomplished from among all the other possibilities. It shows how the technical and market feasibility considerations address all stakeholder choices and barriers. It also addresses all the elements of medical device value creation



Figure 1, Market Engagement Feasibility Model

The assessment of technical and market feasibility for the medical device idea is developed through analyses described below. From these, a series of statements can be formulated about each barrier and choice, that will be tested as development proceeds. Three basic assessments are needed to begin:

- Define the intended use(s) for the device, likely regulatory classification(s), and associated approval requirements.
- Compare your device idea to other alternative treatments. Determine whether it is likely that providers will get paid to use your device, the likely payment amounts, and what procedures must they follow to get paid.
- Evaluate how your device will reach the patient, through identifying key stakeholders, cost-benefit calculations, distribution channels, and environmental factors which will influence stakeholder decisions that result in your device being used to treat patients.

These analyses help identify what is needed to establish the feasibility of the device idea. The results are used to help generate the approach for making the device concept into a successful product. With these results in hand, early stage companies will have gone far toward obtaining the funding needed to develop the product.

Feasibility Must Address Barriers and Choices that Lie Between the Patient and Your Device Idea

Demonstrating Feasibility

Just what do we mean by demonstrating feasibility? Feasibility encompasses more than just technology. The device must also successfully address the market need, meet regulatory requirements, and provide an adequate financial return. Once the technology is embodied in a prototype, investor questions about whether the technology “works” quickly shift to whether the device can be commercially successful. In our experience technology is often, but not always, the chief issue for feasibility.

Technical Feasibility

Certainly one of the key elements is proving the technology. But, our experience is that most entrepreneurs spend efforts on prototype refinements that do not address the right questions. Resist the urge to make the mouse trap better. If you have a prototype that answers the right questions it’s time to think about other, more pressing issues.

Evaluate whether the technical feasibility of your device has been demonstrated by answering the following questions.

- To what degree have any patent claims or other intellectual property been reduced to practice? A key criteria is whether someone skilled in the art would agree that the bench top model demonstrates the claims.
- Has the fitness of the technology to meet intended use been demonstrated? Early stage companies usually have a good idea of how the device can be used. But there is almost always a need to sharpen the definition in such a way that users, FDA, and other regulators have the correct understanding of the intended use for your device. This is an important question, because intended use provides the basis for how FDA and others will evaluate your device.
- To what degree have the safety and technology concerns that may be scrutinized by FDA, or other regulators been addressed? It is important to understand how the technology will affect the structure, or any function of the body, its advantages, and limitations. Do other devices use the same technology? Are there any safety issues presented by the device not already encountered with other treatments? It is important to address these questions early since they typically dictate pre-clinical testing, and influence how the device will be classified, or whether approval can be obtained.

What About Regulatory?

Even in cases where it is a foregone conclusion about how the device will be classified, it still pays huge dividends to run the analysis on intended use, regulatory classification, and approval requirements.

Intended Use: The same technology / design can be used in several different devices. What makes each device different is the intended use or “label claims”. It is not uncommon for a device to have more than one possible application.

Device Classification: The device classification, depending on intended use claims, should be assessed. This helps identify technology and safety issues that may need to be addressed in feasibility, major development milestones, and requirements for approval.

Approval requirements: Once the likely device classification has been postulated, approval requirements can be determined. Some of these may be substantial technical and safety concerns that stand in the way of demonstrating feasibility. Activities and milestones to reach approval help form a development plan to substantiate needed funding.

Finally, looking at regulatory helps to get better focus on addressable patient populations, providers who will ultimately purchase the device, and delivery channels to reach them.

If any further prototype development is needed prior to getting more funding, effort should be targeted to testing specific issues that arise as a result of answering the questions above. Focus future development plans on reducing risk.

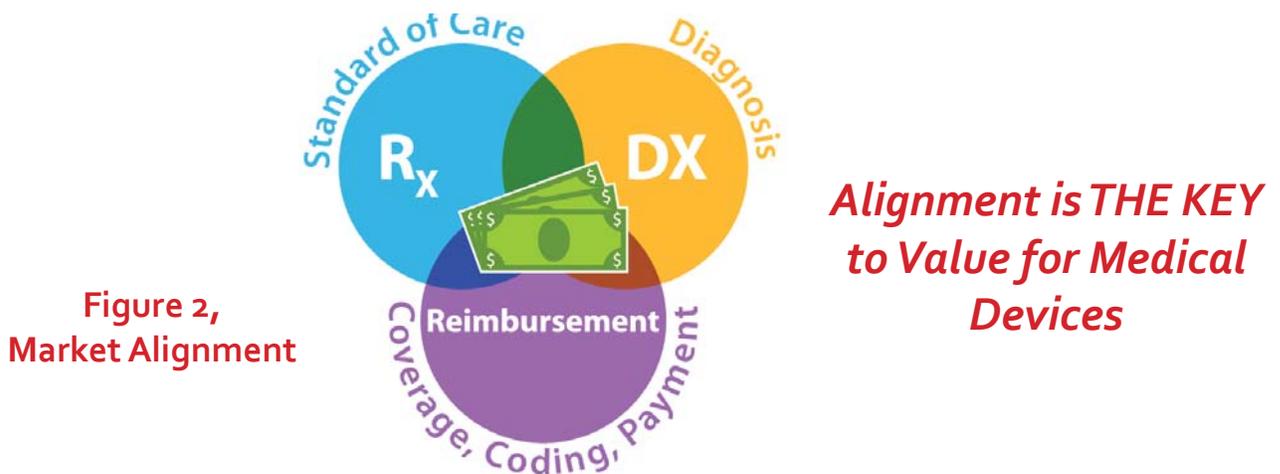
Realistically, for early stage devices, technology gaps will remain until more substantial investments can be made. If gaps remain, the preferred outcome is that a clear path to address remaining technology and safety questions has been identified. Appropriate controls can be applied in subsequent testing, and even during human trials, to manage remaining risk.

Market Feasibility

In many cases, the same technology can be used in different medical devices to meet different intended uses. The market potential of a device idea is driven by choices about which treatments can be provided, and how well the device will meet the treatment need, compared to alternatives. Choices about the intended use for the device will help determine the urgency for making the treatment available, attributes of the patient population, and competition

Choices about the treatment provided by your device will be key drivers of demand, and will help define the patient populations that can be addressed. You must eventually develop a roadmap that defines the launch order for the different devices that use the technology, each having different intended use claims. Determining the launch order is a fundamental planning activity for medical device development.

Even with market potential, the device may not be profitable. The key to unlocking value in the medical device market is to properly align diagnosis, treatment, and reimbursement. Alignment of all three factors is necessary for medical device manufacturers to realize value. Medical devices add value when a properly diagnosed medical condition receives appropriate treatment, with routine optimal payment.



In order to attain alignment there are three different cost-benefit calculations that must be satisfied; the patient's, the provider's (doctor/hospital/care facility), and the payer's. Whether your device reaches the patient depends on how well each of these different cost-benefit calculations are solved.

A Better Business Case - How will the patient find your device?

The market feasibility for the device idea is developed by starting with a good understanding of the entire chain of medical decisions: from patient intake, to diagnosis, to treatment that results in the patient using your device. While work and learning in this area will continue throughout the life of the product, the early stage entrepreneur needs to frame out the basic business case, and develop approaches to influence decisions by each stakeholder. First, recognize that barriers and choices lie between your device idea and the patient. Obstacles you will encounter result from how diagnosis is made and the accepted treatments. The path to realizing value is not mysterious. Outcomes resulting from each barrier and choice can be influenced by the device manufacturer. Let's consider the diagram below.



Figure 3, Market Engagement Model

Going from left to right, our device has been developed, received regulatory approval and is commercially available. Routine optimal payment for using the device is established through management of coverage, coding, and reimbursement. A group purchasing organization (GPO) contracted by the provider, or a distributor, may help choose whether your device will be made available to healthcare practitioners. From the right side of the diagram, the patient arrives at the provider's location, presenting signs and symptoms that allow a correct diagnosis to be made. The provider chooses from diagnostic and treatment alternatives available within the standard of care.

With this overview in mind, let's consider the factors that influence cost-benefit of using a device for patients, providers, and payers. It all starts with the patient. Cost benefit for the patient considers: signs and symptoms of the malady, motivation to seek treatment, treatment regimen, and potential outcomes. The troubles that come with delaying treatment must be greater than the cost of treatment.

Providers are interested in improving outcomes and efficiency over the current standard of care for the same, or lower cost. Does the device fit within the current standard of care, or is it new? What other treatment alternatives are available? Is there a patient sub-group that is more effectively treated using the device? Do facilities that use the device need to be accredited? Do providers that use the device need to be credentialed? Does it allow the provider an opportunity to preserve current revenue streams or, ideally increase potential revenue?

Payers are going to emphasize providing what's needed. New technology is OK if it works well in the system of care, and proves it's worth. Innovations in healthcare delivery such as ACO's and bundling are being implemented as a means of improving outcomes with reduced cost. Many device innovations claim to cut costs, but cannot document that they do. Going forward, devices need to enable data collection, where possible, to document cost impacts.

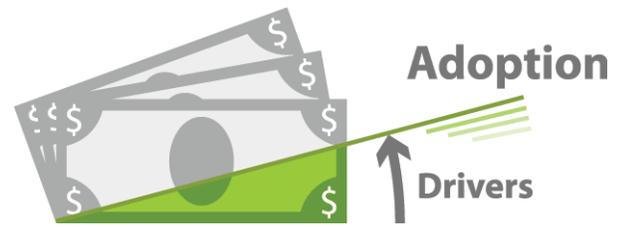
These questions will help in performing a cost-benefit analysis for stakeholders who are facing barriers and choices between your device idea and the patient. Try to identify points where you can act to ensure patients benefit, and value is realized for provider and payer. Apply the Market Engagement Model for medical devices to help identify drivers of market potential and adoption for your device idea.

Entrepreneurs need to understand why their device will be accepted in the market. The market engagement model is useful to get answers to basic questions about market feasibility. It identifies obstacles to adoption, and most importantly, it can be used to develop approaches to get around them.

Evaluating Market Feasibility

Here's how to evaluate the market feasibility of the device. Much of the information needed can be obtained via a basic reimbursement assessment. Evaluate drivers of market potential by answering the following questions.

- Who are the patient segments? What is the prevalence and incidence of the malady addressed by each intended use? What is the patient population per intended use? Are there medical tests or grading scales applied to further stratify patient populations?
- What kinds of providers are involved? Where will the test or procedure be conducted?
- What is the existing standard of care? What alternative treatments are available? What is the benefit and costs of using the device compared to existing alternatives and competitive devices?



Device makers drive adoption through choices they make

What Is An ACO?

Accountable Care Organizations (ACOs) are physician-led, primary care-centered, and patient-focused collaborative systems focused on the health of patient populations. This matrix of care is reimbursed and paid for based on outcomes rather than volume of services.

It requires a group of healthcare providers from all aspects of the continuum to collectively accept accountability for the quality and cost of care provided.

Evaluate the drivers of market adoption by answering the following questions.

- How will patients benefit? What are the signs and symptoms of the disease? How will this device meet the clinical need, given the intended use, signs and symptoms? Are the patients aware they have a malady prior to diagnosis? Are there any noteworthy factors causing patients to seek treatment?
- Why is this device better and where does it fit with respect to the current standard of care? (i.e. Will it be a 1st line, 2nd line, or 3rd line treatment).
- Does the beneficial outcome or efficiency justify any added cost?
- Are there existing reimbursement codes available for the device, or must new codes be sought? What are the coverage decisions for similar devices and how do they apply?
- What accreditation or credentialing is needed to conduct the test or procedure?
- What will professional associations or patient advocacy groups say about the new device?
- Will ACO's/ bundling/ HMO's make life harder or provide a selling point?

Having completed the market assessment, the entrepreneur is in a better position to understand what the patients, providers, and payers are facing, and their respective value propositions. Entrepreneurs will be in a better position to answer the question, 'Can the medical device product make money?'

The entrepreneur will have identified the means to achieve competitive advantage through technology (patents), intended use claims, coverage, coding, accreditation, and credentialing. The volume of devices needed and corresponding cost constraints can be estimated. Approaches for how to influence customer adoption, and willingness to pay can be formulated. Revenue potential for the product can be credibly estimated.

Key Takeaway

The problem of figuring out what to do with \$100K in seed capital is solved through evaluating what remains to be done to complete feasibility. This is accomplished by 1) an evaluation of technical feasibility using the questions posed above, and 2) an evaluation of the market feasibility using a cost-benefit assessment for how your device will find the patient. The market engagement model assures that all the aspects of medical device value creation have been addressed in demonstrating feasibility of the device idea. Once feasibility has been demonstrated, more significant investments can be made to fund subsequent product development.

2 Things NOT to Spend Your Seed Money On

1. More prototypes. Why 5 fully functional prototypes aren't necessarily what investors want to see.

One of the most impactful ways of alluring venture capitalists to invest in a business idea is to have a functioning prototype. However, innovators must recognize that the intent of a prototype is to show "proof of concept" and to demonstrate that the idea can indeed be shaped into an actual product that can fulfill the customer's need. Start-ups should not approach prototype development with a goal of making it as close as possible to the final product. Multiple refinements of a prototype can prove to be extremely costly with little reduction in risk.

Experienced investors know that it takes a lot of time, money, and effort to make a final product. And so, they are not expecting to see the 5th refinement of your prototype, especially if you are just starting out. It is almost certain that the first prototype will not look, or feel anything like the final device. It just needs to be sufficient to demonstrate technical feasibility. This is the most efficient way of convincing investors that the idea, while still needing development, can actually be implemented.

2. Registering the corporation and staffing up.

Stay lean and avoid incorporating. The two main reasons to form a corporation are to share equity among many parties, and separate liability. Early stage start ups with a device idea and promising technology typically do not have very high valuations, so it's reasonable to delay incorporating until after feasibility has been demonstrated. At that point, your investors will be glad to help with this aspect. For early stage companies, a simple LLC often seems adequate for holding assets, such as patents, and separate liability.

Early stage startups should avoid investing money into exponentially expanding staff. It is important to stay "lean". At a high level, this translates to being flexible and adapting to changing customer needs. It is important that startups continuously acquire feedback from customers and reshape the idea to ensure it provides maximum return on investment. For every successful startup we hear about, many more have failed. Often these had bloated sales and support staff long before the first dollar of revenue could reasonably be expected.

About The Team

Brian Scrivens serves as MPR's Director of Product Consulting. He has over 20 years experience as a design engineer specializing in product development and manufacturing for medical devices and diagnostic systems. Mr. Scrivens' experience covers medical devices, diagnostics, disposable device design and manufacturing, process development, and telecommunications with direct contributions to successful product launches totaling more than \$500MM in aggregate sales. Prior to joining MPR, Mr. Scrivens was employed by Advisory Associates, consulting with medical device companies and acquirers on corporate valuations, acquisition and licensing issues. Additionally, Mr. Scrivens was previously with Beckman Coulter and Becton Dickinson, working in design and manufacturing of instruments and consumables for hematology and infectious disease diagnostics.

Doug Riker joined MPR in 2013 with over 30 years of experience in electrical engineering, embedded systems and product development. He has been a part of development teams in start-up, mid-sized, and global organizations. He has deep knowledge in all aspects of product development and technical project management: user needs, requirements, regulatory compliance, embedded systems design, risk management, V&V testing, and manufacturing/operations. Although focused on analog and digital electrical design, Mr. Riker has significant experience in firmware, mechanisms, motion control, and project management.

Vaibhav Bhide joined the MPR Product Development group full time in 2013 with a Masters degree in Biomedical Engineering from Duke University. Mr. Bhide has since been involved in projects developing devices for the medical, life sciences and the power industries.

About MPR

MPR Associates, Inc. is a global design and engineering firm, specializing in translational innovation and expeditious solutions to difficult life sciences and medical technology problems. Although many companies claim to deliver services from "idea-to-product," MPR is unique in spanning the full spectrum of product design, from initial concept and technological innovation to detailed design for manufacturing, and provides unmatched engineering and design services.

Product Consulting works with large and small companies using MPR's First Principles approach in formulating creative approaches to product development through product planning, market strategy, and go-to-market services. First Principles eliminates risk early in the process by solving critical problems first, allowing device ideas to reach the market faster – often in as little as twelve months.

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